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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/806,036 | 07/05/2001 | Mark Leslie Smythe | 36677.29 | 3406 |

27683 7590 12/04/2007
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| EXAMINER |
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KAM, CHIH MIN

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| ART UNIT | PAPER NUMBER |
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1656

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| MAIL DATE | DELIVERY MODE |
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12/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/806,036

Applicant(s)

SMYTHE ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-19,32-35,39,40 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32,39 and 51 is/are allowed.
- 6) ☒ Claim(s) 8-19,33-35,40,44-50 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 8-19, 32-35, 39, 40 and 44-52 are pending.

Applicants' amendment filed on September 28, 2007 is acknowledged. Applicants' response has been fully considered. Claims 8, 11, 12, 18, 46 and 48 have been amended. Thus, claims 8-19, 32-35, 39, 40 and 44-52 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 8-19 and 44-50 under 35 U.S.C. 112, second paragraph, regarding optionally step (d) (paragraph 5 in the previous Office Action dated March 28, 2007) , is withdrawn in view of applicant's amendment to the claims, and applicant's response at pages 18-19 of the amendment filed September 28, 2007.
3. The previous rejection of claim 18 under 35 U.S.C. 112, second paragraph, regarding optionally step (d) (paragraph 7 in the previous Office Action dated March 28, 2007) , is withdrawn in view of applicant's amendment to the claims, and applicant's response at page 19 of the amendment filed September 28, 2007.
4. The previous rejection of claim 46 under 35 U.S.C. 112, second paragraph (paragraph 8 in the previous Office Action dated March 28, 2007) , is withdrawn in view of applicant's amendment to the claims, and applicant's response at page 19-20 of the amendment filed September 28, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8-19, 33-35, 40, 44-50 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 8-19, 33-35, 40, 44-50 and 52 are indefinite because the claim recites a method of synthesis of a cyclic peptide or peptidomimetic compound of General Formula I or General Formula II, where the compound of General Formula I or General Formula II does not contain A1 or A2 group, however, the claim also indicates A1 can be a non-reversible N-substituent. Thus, it is not clear whether the final compound of General Formula I or General Formula II would be obtained if the A1 is a non-reversible N-substituent. Claims 9-19, 34-35, 40, 44-50 and 52 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

7. Claims 11 and 12 are indefinite because claims 11 and 12 recite that the step d) is omitted, A1 and/or A2 is left attached to the peptide for linking to a solid support or to another peptide, and the compound of General Formula I or General Formula II may subsequently be obtained, it is not clear how the compound of General Formula I or General Formula II (i.e., without A1 and/or A2) is subsequently obtained if A1 is non-reversible N-substituent. Claim 11 is also indefinite because of the term "it", it is not clear what the term refers to.

Response to Arguments

Applicant indicates claim 11 has been amended to recite a method in which step d) is omitted to provide scenarios under which either the A1, the A2, or both the A1 and the A2 groups are left on the cyclic peptide or peptidomimetic compound of General formula V for later

attaching such a compound to (a) a solid support or (b) to another cyclic peptide or peptidomimetic compound (as exemplified in the Specification at page 16). In exemplary embodiments, the A1 group can be a reversible N-substituent, and the A2 group may be a covalently-bonded group of atoms comprising a reactive functionality that forms an initial large cyclic peptide, wherein the A2 group is spontaneously eliminated as a result of ring contraction. The language of claim 12 is also further clarified to recite particular illustrative embodiments as set forth in the general Markush recitation found in claim 11, the claim from which it depends (page 18-19 of the response).

Applicants' response has been fully considered, however, applicant's arguments are not found persuasive because A1 can be either a reversible N-substituent or a non-reversible N-substituent, if A1 is non-reversible N-substituent, it is not clear how the compound of General Formula I or General Formula II (i.e., without A1 and/or A2) would be subsequently obtained.

8. Claim 46 is indefinite because of the use of the term "derived from". The term cited renders the claim indefinite, it is not clear what structure the A2 has, and how different the A2 is from the cited auxiliary compound.

9. Claim 48 is indefinite because claim 19, which claim 48 depends from, recites the compound of formula, in which Z is a group which allows the formation of a covalent carbon-nitrogen bond, however, it appears that the cited compound of claim 48 does not conform the compound of claim 19, but rather it is an A2 group.

Response to Arguments

Applicants indicate claims 46 and 48 are clarified to more precisely recite a method in which selected ring contraction auxiliaries may be used to generate the A2 group which then

facilitates the spontaneous ring contraction that forms the final cyclic peptide or peptidomimetic, especially, pages 36-38 of the specification, wherein an exemplary use of such ring contraction auxiliaries is clearly explained (pages 19-20 of the response).

Applicants' response has been considered, regarding claim 46, the arguments are persuasive, thus the rejection is withdrawn. Regarding claim 48, however, the arguments are not fully persuasive because the cited auxiliary compound does not have a Z group for attaching to the peptide, it appears that the auxiliaries (i.e., A2) cited on pages 36-38 are already attached to the peptide.

Conclusion

9. Claims 8-19, 33-35, 40, 44-50 and 52 are rejected. It appears claims 32, 39 and 51 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number:
09/806,036
Art Unit: 1656

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Chih-Min Kam, Ph. D.
Primary Patent Examiner

A handwritten signature in black ink, appearing to read 'Chih-Min', followed by a horizontal line.

CHIH-MIN KAM
PRIMARY EXAMINER

CMK

December 3, 2007